## RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

Serial Number: 10/048,072

Filing Date: January 25, 2002

Title: Immunotherapy In HIV Infected Persons Using Vaccines After Multi-Drug Treatment

## 1-3,7-10,12-18,20-22 IN THE CLAIMS

Please amend the claims as follows.

- (Currently Amended) A method of stimulating a HIV1-specific CD8<sup>+</sup> response in a 1. human infected with an HIV retrovirus said method comprising:
- administering to the human, a an attenuated recombinant pox virus, which enters the cells of the human and intracellularly produces HIV specific peptides for presentation on the cell's MHC class I molecules,
- where said peptides are presented in an amount sufficient to stimulate a protective CD8+ HIV antigen-specific CD8+ and CD4+ responses response, and
- where said human iii)
  - i. has a viral load of less than 10,000 viral copies per ml of plasma and a CD4<sup>+</sup> cell count of above 500 cells/ml, and
  - ii. has been treated with one or more anti-viral agents, which contributed to a lower viral copy and higher CD4<sup>+</sup> cell count than before treatment

where said HIV specific peptides comprise HIV Gag, Gp120, Nef or Pol peptides.

- (Previously Presented) A method of claim 1 wherein the human has been treated with 2. anti-viral agents, which resulted in the human having a viral load of less than 1,000 viral copies per ml of blood serum and a CD4<sup>+</sup> cell count of above 500 cells/ml.
- (Original) A method of claim 2 wherein the anti-viral agents comprise a combination of 3. protease inhibitors and inhibitors of reverse transcriptase.
- 4. (Canceled)
- (Canceled) 5.
- 6. (Canceled)

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- 7. (Currently Amended) A method of claim\_1 [[6]] wherein the attenuated recombinant pox virus comprises NYVAC or ALVAC.
- 8. (Currently Amended) A method of claim 1 [[6]] wherein the recombinant pox virus comprises MVA.
- 9. (Currently Amended) A method of claim 1 where the <u>attenuated recombinant pox virus</u> vaccine is administered a second time.
- 10. (Previously Presented) A method of claim 1 wherein the HIV specific peptides are structural viral peptides.
- 11. (Canceled)
- 12. (Currently Amended) A method of claim 1 wherein the <u>method</u> vaccine further comprises <u>administering</u> an adjuvant.
- 13. (Original) A method of claim 1 further comprising administering interleukin 2 or CD40 ligand in an amount sufficient to potentiate the CD8<sup>+</sup> response.
- 14. (Previously Presented) A method of claim 1 where the human has been infected with HIV and has demonstrated repeated and sustained proliferative T-cell responses to Gp120 envelope protein.
- 15. (Previously Presented) A method of claim 14 where the human has demonstrated repeated and sustained proliferative T-cell responses to p24 Gag antigen.
- 16. (Previously Presented) A method of claim 1 where the human is infected with HIV and is further tested by a skin test for a hypersensitive response to p24 Gag antigen.

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- 17. (Previously Presented) A method of claim 1 where the human is infected with HIV and is further tested by a skin test for a hypersensitive response to Gp120 envelope antigen.
- 18. (Currently Amended) A method of maintaining a reduced viral load in a mammal infected with an immunodeficiency retrovirus said method comprising:
- administering to the mammal a <u>an attenuated recombinant pox virus</u>, which enters the cells of the mammal and intracellularly produces immunodeficiency retroviral specific peptides for presentation on the cell's MHC class I molecules,
- where said peptides are presented in an amount sufficient to stimulate a protective CD8<sup>+</sup>
  HIV antigen-specific CD8+ and CD4+ responses response, and thereby maintain a reduced viral load in the mammal, and
- where said mammal
  - i. has an immunodeficiency retroviral load of less than 10,000 viral copies per ml of plasma and a CD4<sup>+</sup> cell count of above 500 cells/ml prior to administration of the recombinant virus, and
  - ii. has been treated with one or more anti-viral agents, which contributed to a lower viral copy and higher CD4<sup>+</sup> cell count before treatment where said peptides comprise immunodeficiency retroviral Gag, Gp120, Nef or Pol peptides.
  - 19. (Canceled)
  - 20. (Currently Amended) A method of stimulating a HIV1-specific CD8<sup>+</sup> response in a human infected with an HIV retrovirus said method comprising:
- administering to the human, a <u>an attenuated recombinant pox virus</u>, which enters the cells of the human and intracellularly produces HIV specific peptides for presentation on the cell's MHC class I molecules,
- where said peptides are presented in an amount sufficient to stimulate a protective CD8<sup>+</sup>
  HIV antigen-specific CD8+ and CD4+ responses response, and
- where said human
  - i. has a viral load of less than 10,000 viral copies per ml of plasma and a CD4<sup>+</sup> cell count of above 500 cells/ml, and

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ii. has been treated with one or more anti-viral agents, which contributed to a lower viral copy and higher CD4<sup>+</sup> cell count than before treatment

where said HIV specific peptides comprise Gag, Pol, Env peptides or a combination thereof.

- (New) The method of claim 2, wherein anti-viral treatment is reduced or stopped 21. after administering the recombinant virus.
- 22. (New) The method of claim 2, wherein anti-viral treatment is interrupted after administering the recombinant virus.